K092417

DEC 11 2009

B. Summary of Safety and Effectiveness

Insight Ultrasonic Inserts

1. **Date of Summary Preparation:** July 23, 2009

2. **Submitting Firm:** Discus Dental, LLC.

3. **Contact Person**

Winkie Wong
Associate, Regulatory Affairs
Discus Dental, LLC.
8550 Higuera Street
Culver City, CA 90232
310.845.8339
310.845.8647 - fax

4. **Name of Medical Device**

Proprietary Name: Insight Ultrasonic Inserts

Common/Usual Name: Ultrasonic Inserts

Classification Name: Scaler, Ultrasonic

5. **Description of Medical Device**

The Insight Ultrasonic Insert is designed to be used in the handpiece of any conventional magnetostrictive ultrasonic scaler, an instrument used to remove tenacious calculus and plaque by ultrasonic vibrations. When place inside the handpiece, the ultrasonic insert is exposed to a varying magnetic field created by a unique pattern of copper wiring wrapping the plug of the handpiece. The varying magnetic field causes the insert "stack" of the metal tips to contract and expand, thus resulting in insert tip vibration in an elliptical motion. The water supply in the insert washes away the debris and cools the insert tip. The distal 4.3 mm portion of the insert tip is affected by the frequency of 25,000 to 30,000 Hz and performs the instrumentation. The tips are offered in two frequencies, six different colors and twenty different tip styles.

6. **Intended Use**

The Insight Ultrasonic Insert is designed to be used in the handpiece of any conventional magnetostrictive ultrasonic scaler, an instrument used for dental cleaning and removal of tenacious calculus and plaque using ultrasonic vibration. The last 4.3 mm of the insert tip vibrates ultrasonically to remove the tenacious calculus from the teeth.

7. **Substantial Equivalence Determination**

Discus Dental, LLC. believes that the Insight Ultrasonic Inserts are substantially equivalent to the following commercially marketed ultrasonic inserts:

Predicate Device	Company	510(k) No.
Protégé Ultrasonic Inserts	Discus Dental	K051776
Ultrasonic Scaler Inserts	Hu-Friedy MFG. CO., Inc.	K953919
Satin Swivel Ultrasonic Inserts	Hu-Friedy MFG. CO., Inc.	K012060

END OF SUMMARY OF SAFETY AND EFFECTIVENESS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Mr. Winkie Wong
Regulatory Affairs Associate
Regulatory Affairs
Discus Dental, LLC
8550 Higuera Street
Culver City, California 90232

DEC 11 2009

Re: K092417
Trade/Device Name: Insight Ultrasonic Inserts
Regulation Number: 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: .December 8, 2009
Received: December 10, 2009

Dear Mr. Wong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, BS, MS, MBA
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

E. **Indications for Use Statement**

510(k) Number: K092417

Device Name: Insight Ultrasonic Inserts

Intended Use

The Insight Ultrasonic Insert is designed to be used in the handpiece of any conventional magnetostrictive ultrasonic scaler, an instrument used for dental cleaning and removal of tenacious calculus and plaque using ultrasonic vibration. The last 4.3 mm of the insert tip vibrates ultrasonically to remove the tenacious calculus from the teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
Per 21 CFR Sections 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092417